

**COOK, ALEX, MCFARRON, MANZO,  
CUMMINGS & MEHLER, LTD.**

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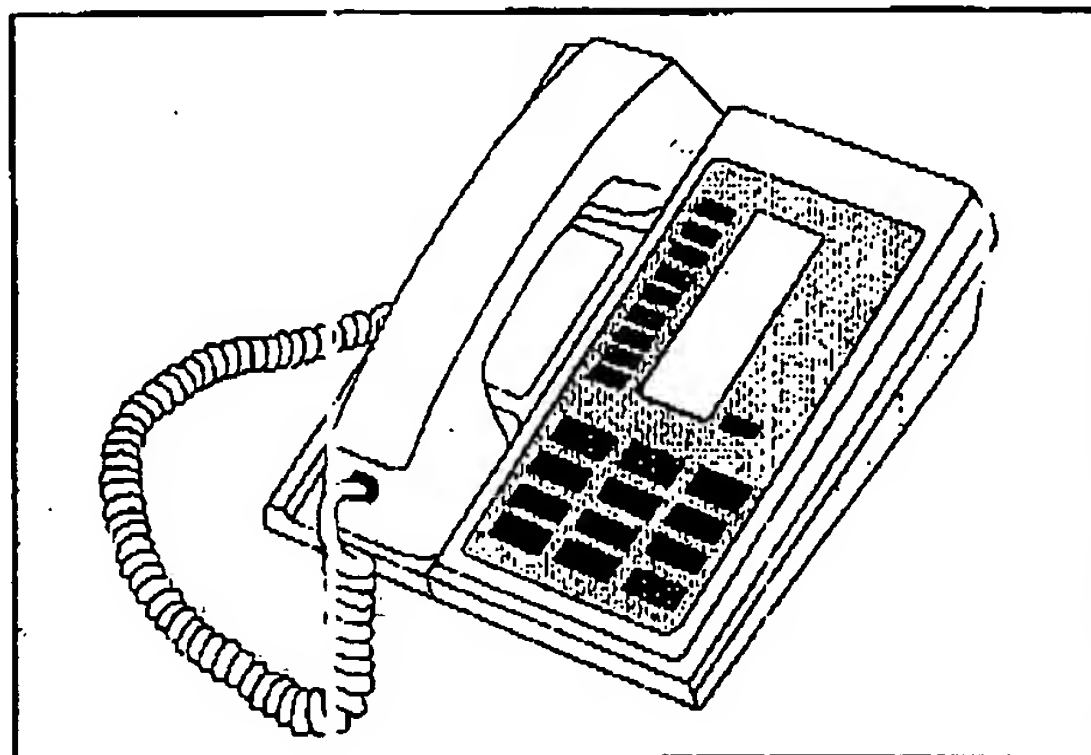
**JUN 30 2005**

**Date: June 30, 2005**

**Client: 3360**

**To: Examiner Thurman K. Page**

**From: Raymond M. Mehler**



**Telecopier Number: 703-872-9306**

**Main Phone Number: 571-272-0602**

**City the Message is Being Faxed to: Alexandria VA**

**Remarks:**

**Mr. Page, here is a the Declaration you had requested for 10/035,821.**

**Ray Mehler**

**Please contact us if you have any problems receiving this message.**

**Our telecopier number is 312-236-8176.**

**Our telephone number is 312-236-8500, Direct 312-334-8536.**

**My e-mail address is: [rmehler@cammcm.com](mailto:rmehler@cammcm.com).**

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JUN 30 2005

Attorney Docket No. IFT-5657A-1 (3360-0023.02) PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
Werling et al. )  
Serial No: 10/035,821 )  
Filed: October 19, 2001 )  
Art Unit: 1615 )  
Confirmation No.: 2470 )  
Examiners: Thurman K. Page )  
Simon J. Oh )  
For: METHOD FOR PREPARING )  
SUBMICRON SUSPENSIONS )  
WITH POLYMORPH CONTROL )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION

Sir:

We, Jane Werling, James E. Kipp, Rajaram Sriram and Mark J. Doty aver as follows:

1. We each are over the age of twenty-one years, and we are the joint inventors of U.S. Patent Application Serial No. 10/035,821, filed October 19, 2001.

2. We have reviewed the claims of this application and believe that the claimed invention was conceived prior to January 7, 2000 and we diligently worked on this project until reduction to practice. All of these activities took place in the United States.

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3. As evidence of this, attached are laboratory notebook pages with dates redacted. The laboratory notebook pages are not necessarily the earliest data of conception of the claimed invention and do not represent the results of an exhaustive search for evidence of the earliest date of conception or reduction to practice.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further, we acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under \$1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: 6/30/05

Jane Werling  
Jane Werling

Date: \_\_\_\_\_

James E. Kipp  
James E. Kipp

Date: \_\_\_\_\_

Rajaram Sriram  
Rajaram Sriram

Date: \_\_\_\_\_

Mark J. Doty  
Mark J. Doty

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Date: \_\_\_\_\_

Date: 6/27/05

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Jane Werling

James E. Kipp

Rajaram Srikam

Mark J. Doty

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08/24/2005 11:08 FAX

COOK ALEX MCFARRON MANZO

0003

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Date: \_\_\_\_\_

Jane Worling

Date: \_\_\_\_\_

James L. Kipp

Date: June 26, 2005

Rajaran Sriram

Date: \_\_\_\_\_

Mark J. Doty

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Date: \_\_\_\_\_

Jane Werling


Date: \_\_\_\_\_

James E. Kipp

Date: \_\_\_\_\_

Rajaram Brijam

Date: 6/27/05

  
Mark J. Doty

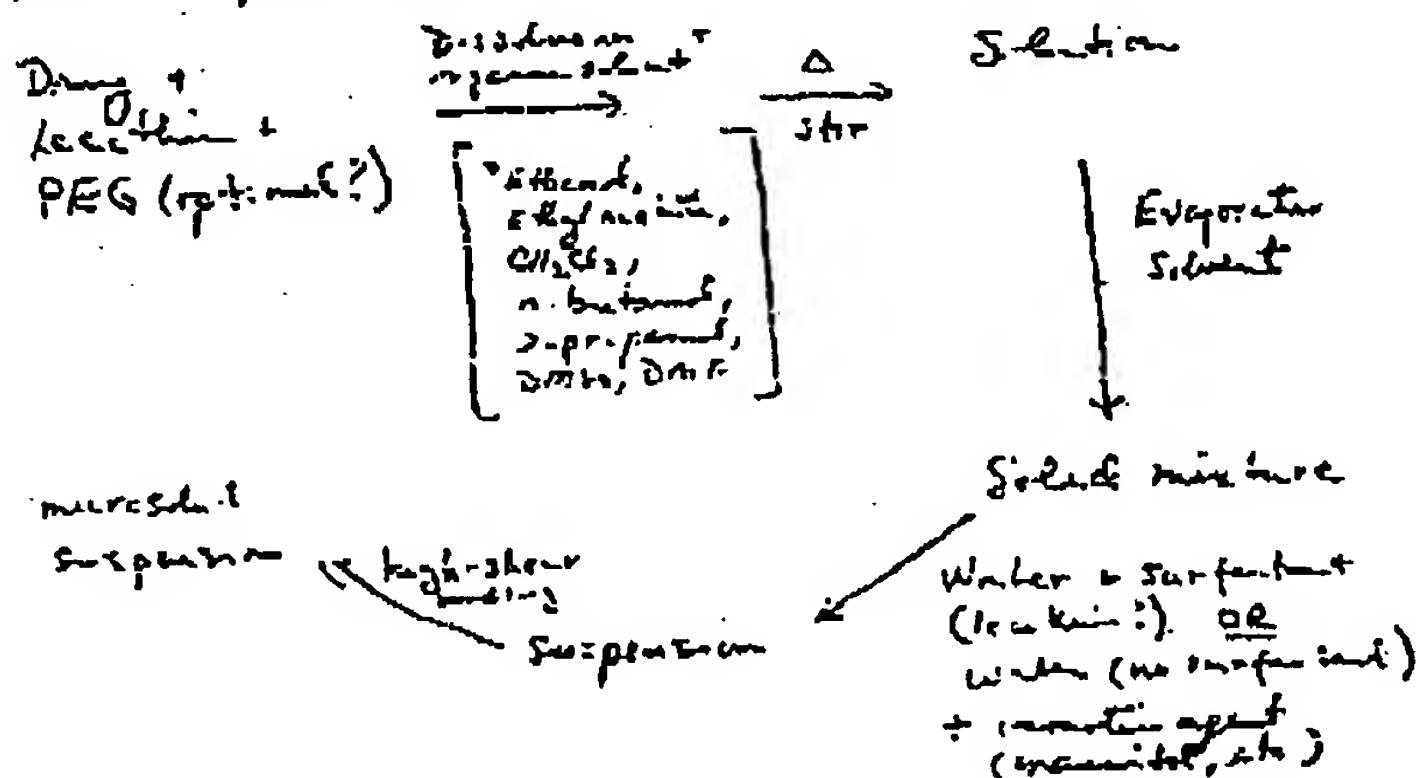
BOOK NO. 20744 - 39

S.I. Disposition of Preclinical - Preclinical

FPM 170

Notebook

Purpose: Test the hypothesis that we can make macrocrystals (or massive particle size) in a macro-suspension by first preparing a solid dispersion of the drug in a matrix such as PEG (polyethylene glycol) and/or phosphatidylcholine (or lecithin). The solid is then resuspended in an aqueous solvent (water + surfactant). Hopefully! High shear mixing (stirring; homogenization?) will cause breakdown of the solid to form macro-crystals (or microcrystals) of the drug in suspension.

General procedure:

I will first attempt to prepare a 1% preclinical suspension using a 5% (w/w) solid dispersion of drug + lecithin (or egg phosphatides). This solid will be <sup>quickly</sup> dispersed in an aqueous medium (water + surfactant). Cell-free formulation FORMULATION!

40

J. S. Kijne

Mark Jeff

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BOOK NO. 20813 - 60

TITLE pH-precipitation of Lactate Acid Prior to Homogenization

PROJECT NO. —

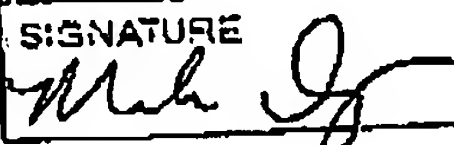
DATE —

Purpose: Note an idea. Use pH-induced <sup>micro</sup>precipitation of Intracinarule prior to homogenization to reduce particle size. Use lactate acid to solubilize the drug. (See Chem. Pharm. Bull, 46(8), 1333-1334 (1998)).

Lactate Acid → pH → Homogenization → Add → Stabilize → Store  
+ Drug or other means    change or other means    or other mechanical means    surfactant(s)

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SIGNATURE



DATE

REVIEW

TO Page No. —

DATE

REVIEWED BY

\*\* TOTAL PAGE 03 \*\*